

Appl. No. : 10/005,684  
Filed : November 8, 2001

#### REMARKS

Claim 1 has been amended. Claim 2 has been canceled. Thus, Claims 1 and 3-12 remain presented for examination. Support for the amendments is found in the specification and claims as filed, for example in Fig. 6. Accordingly, no new matter has been added. Reconsideration of the application in view of the foregoing amendments and following comments is respectfully requested.

#### Rejection under 35 U.S.C. § 112, second paragraph

Claims 1-12 were rejected under 35 U.S.C. § 112, second paragraph as indefinite. The Examiner states that in claim 1, it is unclear whether the conditions diagnosed based on higher than normal levels of the second set, but not the first set, of said plurality of antibodies are in the alternative or inclusive. Claim 1 as amended clarifies that these are in the alternative. With respect to claim 2, the Office Action states that it is unclear if applicant intends to limit the second set of antibodies to a single antibody. Claim 2 has been canceled, thus obviating this rejection.

In view of the foregoing amendments and comments, Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

#### Rejection under 35 U.S.C. § 112, first paragraph (written description)

The Examiner rejected Claims 1-12 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner states that although claim 1 recites that higher than normal levels of any of both the first set and second set of said plurality of antibodies indicates the presence or possibility of autoimmune disease and cardiovascular disease, this presence or possibility only appears to be diagnosed when there are higher than normal levels of all the antibodies in the first and second set of said plurality of antibodies. In addition, the Examiner states that claim 2 appears to be further limiting the plurality of antibodies in the second set to a single antibody.

Although Applicant does not agree with the position taken by the Examiner, claim 1 has been amended to recite that higher than normal levels of both the first set and second set of said

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plurality of antibodies indicate the presence or possibility of autoimmune disease and cardiovascular disease, and claim 2 has been canceled. These amendments are being made solely to expedite prosecution of the application.

The Examiner also alleges that Applicant would only be able to determine the possibility or presence of the specific cardiovascular disease with which the recited antigens are associated, and that there is no diagnosis made for higher than normal levels of any antibody in the first set but not the second set of antibodies. Claim 1 as amended recites that the cardiovascular disease is associated with the presence of the first set of antigens, and no longer recites higher than normal levels of any antibody in the first set but not the second set of antibodies.

Lastly, the Examiner states that although Applicant provides data showing possible autoimmunity and possible cardiovascular disease and autoimmune disease, there are no clearly disclosed steps for comparing the data to distinguish possible cardiovascular and autoimmune disease from possible autoimmune disease. Although Applicant does not agree with the grounds of rejection, claim 1 as amended no longer recites distinguishing possible autoimmune disease from possible autoimmune and cardiovascular disease, but instead recites a method for determining the presence or possibility of autoimmune disease or the presence or possibility of cardiovascular disease with autoimmune disease which was acknowledged by the Examiner to have written description.

Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejections under 35 U.S.C. § 112, first paragraph (written description).

Rejection under 35 U.S.C. §112, first paragraph (enablement)

Claims 1-12 were rejected under 35 U.S.C. §112, first paragraph, as lacking enablement. The Office Action states that the specification, while being enabling for a method for detecting antibodies against certain antigens and for indicating the presence or possibility of autoimmune disease, does not reasonably provide enablement for a method for distinguishing possible autoimmune disease from possible cardiovascular disease with autoimmune disease. Although Applicant does not agree with this conclusion, claim 1 no longer recites a method for

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distinguishing possible autoimmune disease from possible cardiovascular disease with autoimmune disease.

The Examiner also states that according to the data from figure 6, it is assumed that the levels of all 8 (actually 7) antigens would have to be measured in order to distinguish between the likelihood of any autoimmune disease and the likelihood of any cardiovascular disease with any autoimmune disease. As discussed above, the claims no longer recite distinguishing between the two outcomes. In addition, claim 1 now recites that higher than normal levels of both the first set and second set of said plurality of antibodies indicate the presence or possibility of autoimmune disease and cardiovascular disease.

Lastly, the Examiner states that although the recitation of "optimal conditions" is included in the claim, there still appears to be some conflict remaining as toward diagnosing the medical condition of the patients based on the information recited in table 6 and recited in the claims based on the first and second sets of antibodies being independently higher or lower. As discussed above, claim 1 as amended recites that higher than normal levels of both the first set and second set of said plurality of antibodies indicate the presence or possibility of autoimmune disease and cardiovascular disease which is clearly enabled by the specification as filed.

In view of the foregoing amendments and comments, applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph (enablement).

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CONCLUSION

In view of the foregoing amendments and comments, it is respectfully submitted that the present application is in condition for allowance. The undersigned has made a good faith effort to respond to all of the rejections set forth in the Office Action. If any matters remain that could be resolved by telephone, the Examiner is invited to contact the undersigned at the number provided below..

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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